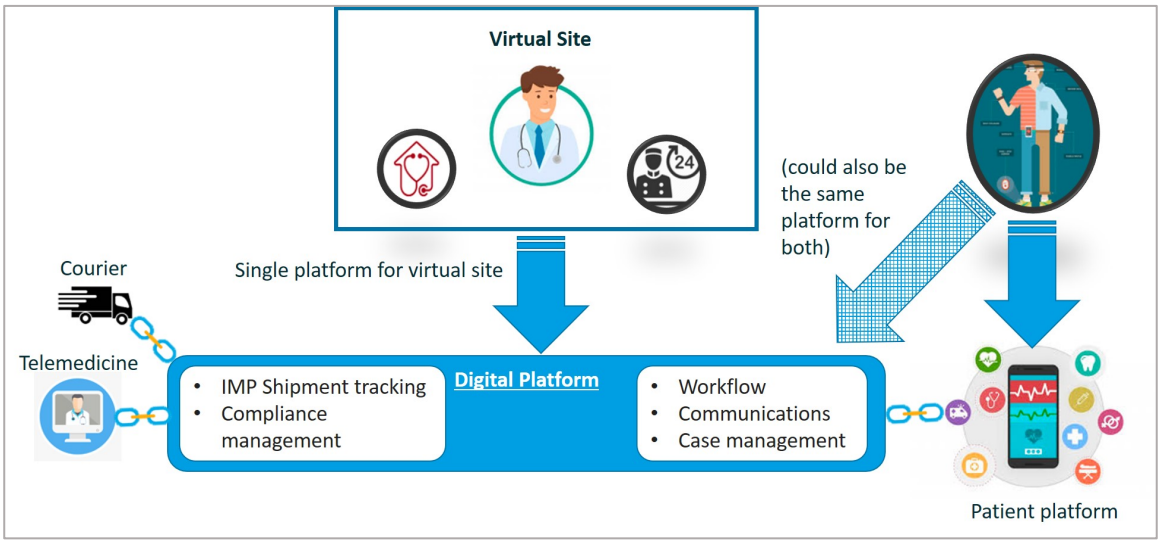
Basic Building Block Profile

Building Block: Intervention & Follow-Up

Vision

We envision a digital platform, containing multiple connected systems where all essential study records (e.g. eCRFs, uploaded eSource documents, electronic health records, scheduling), are contained under a single login. This digital platform connects the decentralised site resources (PI, Study Coordinator/Research Nurse, home health staff, concierge services) with each other. It facilitates a seamless workflow between investigational site personnel and promotes a well-integrated, positive patient-investigator experience. This is a platform for tracking biological samples, devices and IMP shipment, videocall connectivity with study participants, and allows for home and remote visit note taking (details to be captured for record keeping and for eCRF completion).



The research leading to these results has received support from the EU/EFPIA Innovative Medicines Initiative [2] Joint Undertaking (H2020-JTI-IMI2) Trials@Home grant n° 831458.

Activities involved in the BBB

Functional requirements

- **Help desk service,** to provide first point of contact for decentralised site staff technical support
- **Participant concierge service,** e.g. equivalent of a physical site front desk staff, first point of contact for participants, also making outbound calls to schedule and remind about visits, shipments, compliance management, etc.
- **Logistics**, e.g. IMP shipments direct-to-patient or local pick-up depot, possibility for affordable disposable / re-usable cold-chain tracking solution to be included. Biological sampling shipment from patient's home to local or central labs
- **Smart medication solutions for an injectable IMP** with near real-time connectivity:
    - Smart dosing solution (cap for insulin pen)
    - Adherence & inventory data capture app
- **Telemedicine tool,** to include the ability to connect external devices (i.e. cameras, vital sign monitoring systems, wearables)

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Technical requirements

- **Recording and transciption capability (optional)** for video and phone calls (i.e. telemedicine visits, remote coordinators phone calls, etc.)
- Logistics, telemedicine, smart medication and Point of Care devices are required to **integrate into eClinicalHealth Clinpal platform**

Excluded activities from the RFP

Home Health Visits
Self-intervention & Self Monitoring
Clinic Visits

Knock-Out Criteria

Submissions will be rejected if:

- Not able to demonstrate prior cases of at least two different clinical trials wherein IMP (from study drug assignment to drug destruction) and met EMA inspection standards.
- Demonstration of IMP management systems do not conform to reviewers' expectations.
- Non-compliant with GDPR
- Non-compliant with 21 CFR part 11

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